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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
JALLA, SANJOO	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 05/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/744,847	SIM ET AL.	
	Examiner	Art Unit	
	Sanjoo Shree Jalla	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 July 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *49-68* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) *49-68* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Restriction is required under 35 U.S.C. 121 and 372.

2. This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

3. Claim 68 depends on cancelled claim 1. Restriction is based on the consideration that the Examiner considers claim 68 dependent on claim 49.

4. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

   Embodiment I. Claims 49, 52, 54 and 64 are drawn to an isolated protein and a therapeutic composition comprising an amino acid sequence from the group consisting of SEQ ID Nos: 2, 5, 10, 15, 29, 32, 35, 38 and 60-71 or a protein encoded by a nucleic acid sequence selected from the group consisting of SEQ ID Nos: 1, 4, 7, 9, 12, 17, 28, 31, 34, 37, 50-53 and 98.

   Note absent evidence to the contrary, each of the recited protein sequences and protein encoded by each of the recited nucleotide sequences is distinct. Embodiment I encompasses numerous
   GROUPS, not species. If Embodiment I is elected, applicant is required to elect a specific protein with a specific SEQ ID No. If said specific protein with the specific SEQ ID No. is also encoded by a specific nucleotide, then applicant is also required to specify the nucleotide sequence with a specific SEQ ID No.

   Embodiment II. Claims 50, 52-53, 55-60 and 65 are drawn to an isolated nucleic acid sequence and a therapeutic composition comprising a nucleic acid sequence from the group consisting of SEQ ID Nos: 1, 3-4, 6-9, 11-13, 17-18, 28, 30-31, 33-34, 36-37, 39, 50-56, 98 and 100 or a nucleic acid molecule encoding amino acid sequence selected from the group consisting of SEQ ID Nos: 2, 5, 10, 15, 29, 32, 35, 38 and 60-71.

   Note absent evidence to the contrary, each of the recited nucleic acid sequences and nucleotide sequences encoding each of the recited protein sequences is distinct. Embodiment II encompasses numerous GROUPS, not species. If Embodiment II is elected, applicant is required to elect a specific nucleic acid molecule with a specific SEQ ID No. If said specific nucleotide with the specific SEQ ID No. encodes a specific protein with the specific SEQ ID No, then applicant is also required to specify the protein sequence with a specific SEQ ID No.

Embodiment III. Claim 52 is drawn to a therapeutic composition comprising an isolated antibody that selectively binds to TCR Vβ proteins comprising an amino acid sequence from the group consisting of SEQ ID Nos: 2, 5, 10, 15, 29, 32, 35, 38 and 60-71 or a protein encoded by a nucleic acid sequence selected from the group consisting of SEQ ID Nos: 1, 4, 7, 9, 12, 17, 28, 31, 34, 37, 50-53 and 98.

Note absent evidence to the contrary, each of the recited antibody that selectively binds to TCR Vβ protein and protein encoded by each of the recited nucleotide sequences is distinct. Embodiment III encompasses numerous GROUPS, not species. If Embodiment III is elected, applicant is required to elect a specific antibody that selectively binds to a TCR Vβ protein with a specific SEQ ID No. If said specific TCR Vβ protein with the specific SEQ ID No. is also encoded by a specific nucleotide, then applicant is also required to specify the nucleotide sequence with a specific SEQ ID No.

Embodiment IV. Claim 52 is drawn to a therapeutic composition comprising an inhibitor of TCRVβ protein activity wherein the TCR Vβ protein comprising an amino acid sequence from the group consisting of SEQ ID Nos: 2, 5, 10, 15, 29, 32, 35, 38 and 60-71 or a protein encoded by a nucleic acid sequence selected from the group consisting of SEQ ID Nos: 1, 4, 7, 9, 12, 17, 28,31, 34, 37, 50-53 and 98.

Note absent evidence to the contrary, each of the recited inhibitor of TCR Vβ protein and protein encoded by each of the recited nucleotide sequences is distinct. Embodiment IV encompasses numerous GROUPS, not species. If Embodiment IV is elected, applicant is required to elect a specific inhibitor of a specific inhibitor of a specific protein with a specific SEQ ID No. If said specific TCR Vβ protein with the specific SEQ ID No. is also encoded by a specific nucleotide, then applicant is also required to specify the nucleotide sequence with a specific SEQ ID No.

Embodiment V. Claims 51 and 61-63 are drawn to a method to detect expansion of T cells in an animal comprising identifying the presence of one or more TCR nucleic acid molecule(s) selected from the group consisting of $nCaV\beta3_{381}$, $nCaV\beta4_{408}$, $nCaV\beta4_{384}$, $nCaV\beta12_{408}$, $_nCaV\beta3_{381}$, $nCaV\beta12_{402}$, $nCaV\beta72_{438}$, $nCaV\beta72_{399}$, $nCaV\beta3_{333}$, $nCaV\beta4_{351}$, $nCaV\beta12_{339}$, $nCaV\beta72_{423}$, $nCaV\beta21_{396}$, $nCaV\beta54_{354}$ and $nCaV\beta182_{369}$ wherein the variable region has a nucleic acid sequence selected from the group consisting of SEQ ID Nos: 28, 30, 31, 33, 34, 36, 37, 39, 40, 42, 43, 45, 46, 48, 50, 51, 52, 53, 54, 55, 56 and complements of SEQ ID Nos. 50, 51, 52, 53, 54, 55 and 56.

Note absent evidence to the contrary, each of the recited TCR Vβ nucleotide sequences is distinct. Embodiment V encompasses numerous GROUPS, not species. If Embodiment V is elected, applicant is required to elect a specific TCR Vβ nucleic acid molecule(s) with a specific variable region SEQ ID No.

Embodiment VI. Claim 66 is drawn to a method to regulate an immune response in an animal comprising administering to the animal a therapeutic composition comprising the protein

comprising an amino acid sequence from the group consisting of SEQ ID Nos: 2, 5, 10, 15, 29, 32, 35, 38 and 60-71 or a protein encoded by a nucleic acid sequence selected from the group consisting of SEQ ID Nos: 1, 4, 7, 9, 12, 17, 28, 31, 34, 37, 50-53 and 98.

Note absent evidence to the contrary, each of the recited protein sequences and protein encoded by each of the recited nucleotide sequences is distinct. Embodiment VI encompasses numerous GROUPS, not species. If Embodiment VI is elected, applicant is required to elect a specific method using a specific protein with a specific SEQ ID No. If said specific protein with the specific SEQ ID No. is also encoded by a specific nucleotide, then applicant is also required to specify the nucleotide sequence with a specific SEQ ID No.

Embodiment VII. Claim 67 is drawn to a method to regulate an immune response in an animal comprising administering to the animal a therapeutic composition comprising the nucleic acid sequence from the group consisting of SEQ ID Nos: 1, 3-4, 6-9, 11-13, 17-18, 28, 30-31, 33-34, 36-37, 39, 50-56, 98 and 100 or a nucleic acid molecule encoding amino acid sequence selected from the group consisting of SEQ ID Nos: 2, 5, 10, 15, 29, 32, 35, 38 and 60-71.

Note absent evidence to the contrary, each of the recited nucleic acid sequences and protein encoded by each of the recited nucleotide sequences is distinct. Embodiment VII encompasses numerous GROUPS, not species. If Embodiment VII is elected, applicant is required to elect a specific nucleic acid molecule with a specific SEQ ID No. If said specific nucleotide with the specific SEQ ID No. encodes a specific protein with the specific SEQ ID No, then applicant is also required to specify the protein sequence with a specific SEQ ID No.

Embodiment VIII. Claim 68 is drawn to a method for prescribing treatment for specific disease, comprising identifying the presence of a T cell receptor nucleic acid molecule having a unique nucleic acid sequence within a variable region of a beta chain nucleic acid molecule selected from the group consisting of $nCaV\beta3_{333}$, $nCaV\beta4_{351}$, $nCaV\beta12_{339}$, $nCaV\beta72_{423}$, $nCaV\beta21_{396}$, $nCaV\beta54_{354}$, $nCaV\beta182_{369}$, $nCaV\beta3_{381}$, $nCaV\beta4_{408}$, $nCaV\beta12_{408}$, $nCaV\beta72_{438}$, $nCaV\beta21_{462}$, $nCaV\beta54_{417}$ and $nCaV\beta182_{423}$.

Note absent evidence to the contrary, each of the recited methods of using the TCR Vβ nucleotide sequences is distinct. Embodiment VIII encompasses numerous GROUPS, not species. If Embodiment VIII is elected, applicant is required to elect a specific TCR Vβ nucleic acid molecule(s) with a specific SEQ ID No.

5. The inventions listed as Embodiments I-VIII above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reason:

The invention of Embodiment II, indicating an isolated nucleic acid molecule and a nucleic acid sequence selected from SEQ ID NO: 1 and SEQ ID NO:50 has no special technical feature that defines the contribution over the prior art of Wedderburn *et al.* Proc. Natl. Acad. Sci, 1993; 90: 8214-8218.

Wedderburn (Accession No. Z23040) teaches a nucleic acid molecule having a nucleic acid sequence that is 100% identical to nucleic acid of SEQ ID No: 1 and SEQ ID No: 50. The term "having" is open ended. It would open the claim to include the 441 sequence.

6. Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have a single general inventive concept and so lack unity of invention.

7. Accordingly, Embodiment II is not so linked as to form a single general inventive concept and restriction is proper.

8. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

10. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Sanjoo S Jalla whose telephone number is 571-272-4453. The examiner can normally be reached Monday through Friday from 8:30-5pm.

12. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

13. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic /Business Center (EBC) at 866-217-9197 (toll-free).

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